

PHA5104 Sterile Compounding

Spring 2024

1 Credit Hour – [A-E Grading]

The purpose of this course is to introduce the student to sterile compounding in pharmacy practice. The content examines the current standards and best practices for preparing a sterile compound. Topics include pertinent information from USP Chapter 797/800, calculations, microbiological considerations, selection of sterile compounding equipment, engineering controls, aseptic technique, stability and compatibility considerations, quality assurance and product verification. Special topics include preparation of total parenteral nutrition, hazardous preparations, and special needs of infants and children. This course prepares the student for developing skills related to sterile compounding during the professional practice skills laboratory courses and sterile compounding during the Hospital Introductory Pharmacy Practice Experience (HIPPE). This will enable the student to prepare sterile compounds as a pharmacist.

Teaching Partnership Leaders

Janet Schmittgen, Pharm.D.

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- Phone: 352 - 273 - 9547

Office Hours: See Canvas for posted office hours

Cary Mobley, Ph.D.

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See Appendix A. for Course Directory of Faculty and Staff Contact Information.

Entrustable Professional Activities

This course will prepare you to perform the following activities which the public entrusts a Pharmacist to perform:

1. Fulfill a medication order

Course-Level Objectives

Upon completion of this course, the student will be able to:

1. List the standards and regulations for sterile compounding.
2. List the roles and responsibilities of personnel involved in sterile compounding.
3. Describe supplies and equipment used to safely compound and administer compounded sterile preparations.
4. Perform calculations commonly utilized for the compounding and administration of compounded sterile products.

5. Describe important concepts related to microbiological contamination of compounded sterile preparations including modes, influencing factors, consequences, risk levels, and prevention.
6. Describe the different types of primary and secondary engineering controls that are important for sterile compounding.
7. Outline steps of aseptic technique and specific compounding manipulations.
8. Describe labeling requirements for compounded sterile preparations.
9. Describe guidelines and engineering controls important for the proper handling of hazardous agents used in sterile compounding.
10. Describe concepts of quality for compounded sterile preparations.
11. Describe methods of final product verification of compounded sterile preparations.
12. List factors that influence the compatibility and stability of parenteral preparations.
13. Describe Beyond Use Dates (BUDs) and how to assign them using available resources.
14. Describe essential concepts and methods of evaluating stability and compatibility.
15. Describe essential concepts and techniques for the preparation of parenteral nutrition preparations.
16. Describe special considerations for parenteral drug therapy in infants and children.

Course Pre-requisites

1. Completion of all Year 1 Pharm.D. program coursework including milestones.

Course Co-requisites

1. PHA5164 Professional Practice Skills Laboratory 4

Course Outline

See Appendix. Please routinely check your campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/times, deadlines, and room changes.

Required Textbooks/Readings

Use [UF VPN to access UF Libraries Resources](#) when off-campus.

The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the [HSC Library Website](#) at this URL: <http://www.library.health.ufl.edu/>

Suggested Textbooks/Readings

Ochoa PS and Vega JA. *Concepts in Sterile Preparations and Aseptic Technique*. Jones & Bartlett Learning. Burlington, MA, 2015. ISBN-13: 9781284035728

- Not Available via HSC Library

Other Required Learning Resources

Non-programmable calculators are required for this course.

Materials & Supplies Fees

None

Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.

[The Canvas® gradebook will be set-up using the percentages below to compute the grade.]

Table 1.1 Evaluation and Grading Above

Assessment Item	Grade Percentage
Online Quizzes [n=3 @ 2% each]	6%
In-Class Quiz #1	10%
Online Calculations Quiz with Documentation	14%
In-Class Quiz #2	10%
Active Learning Documentation	10%
Final Exam	50%
Total	100%

Table 1.2 grading scale

Percentage	Letter Grade
92.50-100%	A
89.50-92.49%	A-
86.50-89.49%	B+
82.50-86.49%	B
79.50-82.49%	B-
76.50-79.49%	C+
72.50-76.49%	C
69.50-72.49%	C-
66.50-69.49%	D+
62.50-66.49%	D
59.50-62.49%	D-
< 59.50%	E

Rounding of grades:

Final grades in Canvas will be rounded to the 2nd decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and NO EXCEPTIONS will be made in situations where a student's grade is "close."

Assignment Descriptions

Online Quizzes (6%)

Students will complete open-book online quizzes by their due date. These quiz questions will be similar in complexity as the in-class quizzes, providing students with extra practice to self-assess knowledge.

In-Class Quiz (20%)

Students will begin class by taking an individual quiz based on the content in the module. Please refer to the course schedule for specifics on what will be covered for each ALS.

Online Calculations Quiz with Documentation (14%)

Students will complete an online quiz on calculations and submit documentation showing the work for all problems by the due date in the course schedule. Points will be deducted if work is not shown on all problems.

Active Learning Documentation (10%)

Students will submit documentation related to their active learning exercises by the end of each ALS.

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software.

1. ExamSoft™ Testing Platform
2. Canvas™ Learning Management System

For technical support, navigate to [Educational Technology and IT Support Contact Information](#) at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/technical-help/>

Artificial Intelligence Use

The use of artificial intelligence (AI) text generators such as ChatGPT on assignments, projects, quizzes, and exams is prohibited in this course. Use of AI text generators is considered evidence of academic dishonesty. If a student is uncertain about the use of AI technology, it is the student's responsibility to ask the instructor prior to beginning the assignment or assessment.

Pharm.D. Course Policies

The Policies in the following link apply to this course. Review the General [Pharm.D. Course Policies](#) carefully, at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/course-policies/>

Attendance Policy

Attendance is mandatory for active learning sessions such as team-based learning sessions, case discussions, laboratory sessions, and other activities that the instructor designates as required. This course has 2 required sessions. A student who misses greater than 1 session (25% of the required active learning sessions/activities) for this course will receive an incomplete in the course and will retake the course during the next offering, resulting in delayed graduation.

Makeup Assignments

Makeup assignments WILL be required for excused absences from all Active Learning Sessions. Students will be required to complete the makeup assignment within one week of the missed session.

Late Assignments

Late assignments will not be accepted.

Accessibility and Belonging Statement

The University of Florida College of Pharmacy strives to stimulate a culture that promotes diversity and inclusion within an exceptional community of students, faculty, and staff. It is our intent that students from all diverse backgrounds and perspectives be well served by this course, that students' learning needs be addressed both in and out of class, and that the diversity that students bring to this class be viewed as a resource, strength, and benefit.

We intend to present materials and activities that are respectful of diversity: gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture. Your suggestions are encouraged and appreciated. Please let us know ways to improve the course's effectiveness for you personally or for other students or student groups.

If any of our class meetings conflict with any of your religious events, an excused absence will be provided when requested using the standard UF COP process as detailed in the [UF COP Course policies](#).

If you feel that you have experienced or witnessed any bias/treatment that falls short of these expectations, you may submit a report through the UF [COP Student Mistreatment Report](#).

Course Evaluation Process

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at <https://gatorevals.aa.ufl.edu/students/>. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via <https://ufl.bluera.com/ufl/>. Summaries of course evaluation results are available to students at <https://gatorevals.aa.ufl.edu/public-results/>.

Appendix A. Course Directory

Teaching Partnership Leader/Course Director(s):

Janet Schmittgen, Pharm.D.

- Email: jschmittgen@ufl.edu
- Office:
- Phone: 352 - 273 - 9547

Office Hours: See Canvas for posted office hours

Cary Mobley, Ph.D.

- Email: wmobley@ufl.edu
- Office:
- Phone: 352 – 273 - 6282

Questions to Ask:

- Concerns about performance
- Guidance when there are performance problems (failing grades)
- General questions about content

Other Teaching Partnership Faculty Members:

Leonardo Esperon, Pharm.D.

Email: espelo@shands.ufl.edu

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Lisa Vandervoort, Pharm.D.

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Instructional Designer:

Skylar Johnson, M.A.

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Academic Coordinator Gainesville Campus:

Hanna Stallard

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Office: HPNP 4312/GNV

Phone: 352-273-6312

Educational Coordinators

Katie Orben

- Email: korben06@ufl.edu
- Office: Jacksonville Campus
- Phone: (904) 244 - 9590

Jessica Linares or Dante Maldonado

- Email: jnoriegalinares@ufl.edu or maldonaldod1@ufl.edu
- Office: Orlando Campus
- Phone: 407-313-4087

Questions to Ask:

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence/tardy requests (Only the Academic Coordinator handles absence requests)
- Questions about dates, deadlines, meeting place
- Availability of handouts and other course materials
- Assignment directions
- Questions about grade entries in gradebook (missing grades, incorrect grade)

- Assistance with ExamSoft® (Distance campus students may contact the Educational Coordinator for use of Examplify and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.)

Appendix B: Course Outline

Date / Time [Recommended for Independent Study]	Mod#	Activity	Activity Title	Objectives	Contact Time (hr)	Responsible
	1	Module	Introduction to Sterile Compounding	1-4		
01/02/24	1.1	Lecture Video	Watch: Introduction to Parenteral Preparations, Supplies, and Equipment		0.75	Timothea Scott
01/02/24	1.2	Lecture Video	Watch: Calculations for Parenterals I		1	Cary Mobley
01/02/24	1.3	Lecture Video	Watch: Calculations for Parenterals II		0.75	Cary Mobley
	2	Module	Compounding Sterile Preparations	7-9		
01/03/24	2.1	Lecture Video	Watch: Aseptic Technique and Compounding Manipulations		0.75	Miranda McKean
01/03/24	2.2	Lecture Video	Watch: Preparation of Hazardous Drugs for Parenteral Use		0.5	Leonardo Esperon
01/05/24 at 11:59pm	1.1 - 2.2	Quiz (Online)	Online Quiz 1			Cary Mobley
	3	Module	Stability and Compatibility of Sterile Preparations	12-14		
01/04/24	3.1	Lecture Video	Watch: Principles of Compatibility and Stability		1	Janet Schmittgen
01/04/24	3.2	Lecture Video	Watch: Utilizing Compatibility and Stability Information Resources		1	Janet Schmittgen
1/8/24 from 8am-9:50am	1.2-1.3; 3.1-3.3	Active Learning Session	ALS 1: Hospital Pharmacist Sterile Compounding Calculations		2	Cary Mobley, Janet Schmittgen, Lisa M Vandervoort
01/08/24	1.2-1.3; 3.1-3.3	Quiz (In Class)	In-class quiz 1			Cary Mobley

Date / Time [Recommended for Independent Study]	Mod#	Activity	Activity Title	Objectives	Contact Time (hr)	Responsible
	4	Module	Fundamental Concepts – Microbiological Considerations	5, 6		
01/09/24	4.1	Lecture Video	Watch: Microbiological Considerations in Parenteral Compounding		0.75	Rebeca Garcia- Carranza
01/09/24	4.2	Lecture Video	Watch: Primary and Secondary Engineering Controls		0.75	Nisha Tahiliani
01/09/24	4.3	Reading	USP 797 and USP 800 (See Canvas for Assigned Pages)		1	Nisha Tahiliani
1/10/24 at 11:59pm	ALS 1; 1.2-1.3	Quiz (Online)	Online Calculations Quiz with Documentation			Cary Mobley
	5	Module	Quality in Sterile Compounding and Final Product Verification	10, 11		
01/10/24	5.1	Lecture Video	Watch: Quality in Sterile Compounding and Final Product Verification		0.5	Mary Jo Cruz Marrero
01/10/24	5.2	Reading	Read: Quality in Sterile Compounding and Final Product Verification		0.75	Mary Jo Cruz Marrero
1/11/24 at 11:59pm	3-4 (includi ng reading s)	Quiz (Online)	Online Quiz 2			Cary Mobley
1/12/24 from 9am- 10:50am	4.2-4.3	Active Learning Session	ALS 2 - Cleanroom Design		2	Cary Mobley, Janet Schmittgen, Nisha Tahiliani
01/12/24	4.2-4.3	Quiz (In Class)	In class quiz 2			Cary Mobley
1/12/24 from 11am- 11:30am		Course Evaluation	Sterile Compounding Course Evaluation			
	6	Module	Module 6: Specialties within Sterile Compounding	15, 16		
01/15/24	6.1	Lecture Video	Watch: Multiple Product Preparations for Parenteral Nutrition		0.75	Timothea Scott
01/15/24	6.2	Lecture Video	Watch: Considerations for Intravenous Drug Therapy in Infants and Children		0.75	Ivett Hernandez
1/16/24 at 11:59pm	5 and 6	Quiz (Online)	Online Quiz 3			Cary Mobley
1/17/24 from 9am- 11am	1-6	Exam	Final Exam	1-16	2	Cary Mobley, Janet Schmittgen

Date / Time [Recommended for Independent Study]	Mod#	Activity	Activity Title	Objectives	Contact Time (hr)	Responsible
1/24/24 from 4pm- 4:30pm		Exam Review	Sterile Compounding Final Exam Review			
			Total Contact Hours in Course:		15.25	